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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/607,434 | 06/26/2003 | Mark P. Anstadt | MPA-554 | 5213 |

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| EXAMINER |
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OROPEZA, FRANCES P

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| ART UNIT | PAPER NUMBER |
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3766

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/607,434 | Applicant(s) ANSTADT ET AL. | |
| | Examiner Frances P. Oropeza | Art Unit 3766 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/28/06 (Amendment).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 131, 133, 150-155 and 243 is/are pending in the application.
- 4a) Of the above claim(s) 243 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 131, 133 and 150-155 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2/28/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restriction

1. Newly submitted claim 243 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 243 comprises a first cavity corresponding to the left ventricle and a second cavity corresponding to the right ventricle, the first and second cavities together extending circumferentially completely around the outer wall.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 243 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response

2. The Applicant at least amended the independent claim in the response filed 2/28/06, hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

Claim Rejections - 35 USC § 103

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 131, 133 and 151-155 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al. (US 5713954) in view of Snyders (US 4690134).

Rosenberg discloses a fluid displacement mechanical ventricular assist apparatus (figure 2) comprising an outer wall, and a controller (23) with algorithm that processes an ECG related to the function of the heart and a hydraulic stroke volume (flow rate) and a hydraulic pressure related to the assist apparatus, and exports a command to control the drive fluid of the apparatus. The apparatus comprises multiple cylindrical tubes, each tube being a single continuous cavity, and each tube wrapped circumferentially in a vertical direction (abstract; fig 2; col. 3 @ 25-50 and 62-67; col. 5 @ 44-63; col. 6 @ 57-62; col. 9 @ 23-27 and 51-60; col. 10 @ 5-10; col. 11 @ 23- 31).

As to claim 155, the command instruction maintains the heart constant in that the device is hydraulically actuated in timed relationship to the contractions of a healthy natural heart beat (col. 3 @ 25-36).

As to claim 131, the first and second cavities extend circumferentially completely around the outer wall (figures 2, 3; col. 3 @ 48-52).

As discussed in the previous three paragraphs of this action, Rosenberg et al. disclose the claimed invention except for the controller effecting changes in the volume within the single continuous cavity of variable volume (claim 131).

Snyders teaches ventricular assist using a controller to change volumes within the single continuous cavity of variable volume for the purpose of varying the ventricular ejection volume. It would have been obvious to one having ordinary skill in the art at the time of the invention to have the controller effect changes in the volume within the single continuous cavity of variable

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volume in the Rosenberg et al. system in order to properly adjust the ventricular ejection volume to establish the right and left ejection pressures appropriate for the patient (col. 5 @ 17-28).

4. Claims 131 and 151-155 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kung et al. (US 6626821) and further in view of Snyder (US 4690134).

Kung et al. discloses a fluid displacement mechanical ventricular assist apparatus (figs 1, 32; col. 5 @ 59 – col. 6 @ 6; col. 13 @ 28-40) comprising an outer wall, and a controller (122, 529) that receives sensed cardiac information (531) from multiple sensors and synchronizes the pump operation with the ventricles (read to be an algorithm) by exporting commands from the controller. The apparatus comprises multiple inflation elements, each tube being a single continuous cavity, and each tube wrapped circumferentially in a vertical direction (col. 6 @ 13-19; col. 13 @ 27-40).

As to claim 133, the utilization of an assist device by a physician for a particular patient is understood to include not only implantation but also operation of the device, hence the physician defines the parameters utilized in the system to define heart functioning (col. 1 @ 56-60).

As to claims 153 and 154, the controller process pump flow rate and pump pressure related to the assist apparatus (col. 3 @ 58-61; col. 14 @ 10-44; col. 16 @ 1-3; col. 17 @ 59-64).

As to claim 155, the cardiac wrap is flow balanced to adapt to the individual patient needs, hence keeping the function of the heart constant (col. 3 @ 28 – col. 4 @ 7).

As discussed in the previous four paragraphs of this action, Kung et al. disclose the claimed invention except for the controller effecting changes in the volume within the single continuous cavity of variable volume (claim 131).

Snyders teaches ventricular assist using a controller to change volumes within the single continuous cavity of variable volume for the purpose of varying the ventricular ejection volume.

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It would have been obvious to one having ordinary skill in the art at the time of the invention to have the controller effect changes in the volume within the single continuous cavity of variable volume in the Kung et al. system in order to properly adjust the ventricular ejection volume to establish the right and left ejection pressures appropriate for the patient (col. 5 @ 17-28).

Statutory Basis

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for

After Final communications.

Frances P. Oropeza
Patent Examiner
Art Unit 3766

FPO
4/5/06


Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766